UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA, Plaintiff, v. **SAMEER BANI,** Defendant.	**INDICTMENT** **Criminal No. 19-** 780 (ADC) **Violations:** **Title 18, United States Code, §§ 2, 545, 1956, 2320** **Title 21, United States Code, §§ 331(c), 333(a)2), 841(a)(1), 841(b)(2)** **(7 COUNTS)**

THE GRAND JURY CHARGES:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

1. The United States Food and Drug Administration (FDA) was the federal agency responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-399f (FDCA), and other pertinent laws and regulations. FDA's responsibilities included regulating the manufacture and distribution of drugs and medical devices shipped or received in interstate commerce, as well as ensuring that the labeling of such articles contained true and accurate information.

2. Under the FDCA, "label" was defined as "a display of written, printed, or graphic matter upon the immediate container of any article." Title 21, United States Code, § 321(k). The term "labeling," in turn, was defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Title 21, United States Code, § 321(m).

3. The FDCA prohibited, among other things, receiving in interstate commerce a misbranded article, and delivering or proffering delivery of such misbranded article for pay or otherwise. Title 21, United States Code, § 331(c).

4. The FDCA defined interstate commerce as: "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other territory not organized with a legislative body." Title 21, United States Code, § 321(b).

Drugs

5. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles (other than food) intended to affect the structure or any function of the body of man." Title 21, United States Code, § 321(g)(1)(B) and (C).

6. Under the FDCA, "prescription drugs" were drugs that, because of their toxicity and other potential for harmful effects, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. Title 21, United States Code, § 353(b)(l)(A). A drug was also a prescription drug if the FDA required it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. Title 21, United States Code, § 353(b)(l)(B).

7. Under the FDCA, a drug was deemed to be "misbranded" if its labeling was false or misleading in any particular. Title 21, United States Code, § 352(a).

8. Although labeled and marketed as "dietary supplements," products that contained the active pharmaceutical ingredient (API) of an FDA-approved drug were excluded from the

definition of "dietary supplement" under the FDCA. *See* Title 21, United States Code, § 321(ff)(3)(B)(1). Instead, these products were "drugs" under the FDCA because they were articles, other than food, intended to affect the structure and/or function of the body of man. *See* Title 21, United States Code, § 321(g)(1)(C).

9. Viagra was a branded, prescription drug containing the API sildenafil citrate ("sildenafil"). Viagra was FDA-approved for the treatment of erectile dysfunction.

10. Sildenafil belongs to a class of compounds known as phosphodiesterase type 5 inhibitors ("PDE-5 inhibitors"), which are used to treat erectile dysfunction. PDE-5 inhibitors may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous, and possibly life-threatening, levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

11. Sibutramine is a Schedule IV controlled substance and was the API in Meridia, a prescription drug indicated to treat obesity. Meridia was pulled from the market by its manufacturer at FDA's request in October 2010, because sibutramine was linked to a risk of heart problems and stroke.

12. Phenolphthalein was an API in some over-the-counter laxative products until 1999, when FDA reclassified the drug as "not generally recognized as safe and effective" after studies indicated that it presented a potential carcinogenic risk; phenolphthalein has also been found to be genotoxic in that it can damage or cause mutations to DNA.

Devices

13. The FDCA defined a medical "device" to include "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other

conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Title 21, United States Code, § 321(h)(2) and (3).

14. Under the FDCA, a device was deemed to be "misbranded" if its labeling was false or misleading in any particular. Title 21, United States Code, § 352(a).

15. Male latex condoms were medical "devices" under the FDCA. *See* Title 21, C.F.R. § 884.5300.

16. Durex is a brand of condoms marketed and sold by Reckitt Benckiser Group. Durex® was registered with the U.S. Patent and Trade Office (USPTO) on or about December 19, 2000 by LRC Products Ltd. Co. UK.

COUNT 1
Smuggling
(Title 18, United States Code, § 545)

17. The factual allegations set forth in paragraph 1 through 16 are re-alleged and incorporated herein by reference.

18. On or about April 25, 2018, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court, the defendant,

SAMEER BANI,

aided and abetted by others known and unknown to the Grand Jury, fraudulently and knowingly received, concealed, sold, and facilitated the transportation, concealment, and sale of merchandise contrary to law after importation, namely drugs imported from China that were

misbranded in violation of Title 21, United States Code, Section 352(a), in that the drugs' respective labeling was false or misleading for failure to properly declare active pharmaceutical ingredients, knowing that such merchandise had been imported and brought into the United States contrary to law, as more fully described below:

MERCHANDISE CONTRARY TO LAW
Fruta Planta weight loss product containing undeclared sibutramine and phenolphthalein APIs
Li Da DAI DAI HUA weight loss product containing undeclared sibutramine, phenolphthalein, and sildenafil APIs
SlimExtreme Gold weight loss product containing undeclared phenolphthalein API
Enhanced Vegetal Vigra, Horney Lion, Plant Vigra, Paradise Ultra Plus, Lang Yi Hao, ExtenZe, Shanghai Ultra X, Suerosexx, Lobo, and La Pepa Negra male enhancement products containing undeclared sildenafil API

All in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 2
Receipt in Interstate Commerce and Proffered Delivery of Misbranded Articles
(Title 21, United States Code, §§ 331(c) and 333(a)(2))

19. The factual allegations set forth in paragraphs 1 through 16 are re-alleged and incorporated herein by reference.

20. On or about April 25, 2018, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court, the defendant,

SAMEER BANI,

aided and abetted by others known and unknown to the Grand Jury, with intent to defraud and mislead, did receive in interstate commerce from China to Puerto Rico, drugs that were misbranded within the meaning of Title 21, United States Code, Section 352(a), in that the drugs' respective labeling was false or misleading for failure to properly declare active pharmaceutical

ingredients, and delivered or proffered delivery thereof for pay or otherwise, as more fully described below:

MISBRANDED DRUG	FALSE/MISLEADING LABELING
a) Fruta Planta	a) Sibutramine and phenolphthalein not declared
b) Li Da DAI DAI HUA	b) Sibutramine, phenolphthalein, and sildenafil not declared
c) SlimExtreme Gold	c) Phenolphthalein not declared
d) Enhanced Vegetal Vigra	d) Sildenafil not declared
e) Horney Lion	e) Sildenafil not declared
f) Plant Vigra	f) Sildenafil not declared
g) Paradise Ultra Plus	g) Sildenafil not declared
h) Lang Yi Hao	h) Sildenafil not declared
i) ExtenZe	i) Sildenafil not declared
j) Shanghai Ultra X	j) Sildenafil not declared
k) Suerosexx	k) Sildenafil not declared
l) Lobo	l) Sildenafil not declared
m) La Pepa Negra	m) Sildenafil not declared

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNT 3
Possession with Intent to Distribute a Controlled Substance
(Title 21, United States Code, §§ 841(a)(1) and (b)(2))

21. The factual allegations set forth in paragraphs 1 through 16 are re-alleged and incorporated herein by reference.

22. On or about April 25, 2018, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court, the defendant,

SAMEER BANI,

aided and abetted by others known and unknown to the Grand Jury, did knowingly and intentionally possess with the intent to distribute and dispense, purported weight loss products, namely "Fruta Planta" and "Li Da DAI DAI HUA," which contained sibutramine, a Schedule IV Controlled Substance.

All in violation of Title 21, United States Code, Section 841(a)(1) and (b)(2) and Title 18, United States Code, Section 2.

COUNT 4
Trafficking in Counterfeit Goods
(Title 18, United States Code, § 2320)

23. The factual allegations set forth in paragraphs 1 through 16 are re-alleged and incorporated herein by reference.

24. On or about April 25, 2018, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court, the defendant,

SAMEER BANI,

aided and abetted by others known and unknown to the Grand Jury, did intentionally traffic in goods and knowingly used a counterfeit mark on and in connection with such goods, namely counterfeit Durex® condom foil wrappers.

All violation of Title 18, United States Code, Sections 2320(a)(1) and 2.

COUNTS 5 – 7
International Money Laundering
(Title 18, United States Code, § 1956(a)(2)(A))

25. The factual allegations set forth in paragraphs 1 through 16 are re-alleged and incorporated herein by reference.

26. On or about the dates set forth below, each date constituting a separate count of the Indictment, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court, the defendant,

SAMEER BANI,

did knowingly and willfully transmit monetary instruments or funds from a place inside the United States to a place outside the United States, with the intent to promote the carrying on of specified unlawful activity, namely smuggling merchandise contrary to law into the United States, in violation of Title 18, United States Code, Section 545, as more fully described below:

COUNT	DATE	TRANSMISSION OF FUNDS	LOCATION
5	3/21/2018	$4,500 wire transfer	From Banco Popular de Puerto Rico to Hong Kong and Shanghai Banking Corporation
6	4/6/2018	$2,875 wire transfer	From Banco Popular de Puerto Rico to Bank of China Shanghai
7	4/17/2018	$3,025 wire transfer	From Banco Popular de Puerto Rico to Industrial and Commercial Bank of China Asia Limited

Each count constituting a separate and distinct violation of Title 18, United States Code, Sections 1956(a)(2)(A).

TRUE BILL

Date: Dic 12, 2019

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